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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,124

04/08/2004

Can Ozbal

2119/122

8211

7590

11/07/2005

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EXAMINER

GARBER, CHARLES D

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/821,124	OZBAL, CAN	
	<b>Examiner.</b>	<b>Art Unit</b>	
	Charles D. Garber	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-27, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 28 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/05/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/15/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 10-15, 18-21, 26, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Averette (US Patent 4,624,148).

Regarding claims 1 and 21, Averette discloses an automatic fluid injector including a vial 91 defining a volume for holding a sample, the volume closed by a “septum”; an outer tube 65 having a proximal end and a distal end, the proximal end shaped in a bevel (figure 5) which will permit piercing the septum; and an inner tube 66 having an end region axially movable within the outer tube between a piercing position (figure 4), wherein an end of the inner tube in the end region is retracted from the proximal end of the outer tube, and a transmission position (figure 5), wherein the end of the inner tube extends axially beyond the proximal end of the outer tube; wherein the outer tube and the inner tube form a tube assembly; and wherein at least one of the tube assembly and the container can be moved to cause the outer tube to pierce the seal and, after the seal is pierced, the inner tube can be used in the transmission position to permit fluid transfer with respect to the volume (abstract).

As for claims 2 and 27, the inner tube 66 is mechanically biased in the transmission position by piston 61, such bias being normally overcome by controlling

Art Unit: 2856

the frame 61 motion to be in concert with frame 51 while the outer tube is used to pierce the seal.

As for claim 7, the flexible inner tube 66 is capable of moving freely within the outer tube as in the instant invention.

As for claims 10 and 11, the reference recites the "invention relates to improvements in automatic fluid injectors, or automated syringes useful for automatically injecting very small, accurately measured quantities of a fluid into various media, e.g. the inlets of modern analytical instruments such as mass spectrographs or gas chromatographs."

As for claim 12, the tubes 65 and 66 are concentric as shown in the figures.

As for claim 13, the reference recites "the needle and probes, the piston units, and the like, are preferably constructed of metals".

As for claim 14, the inner tube 66 is defined as a "flexible hollow needle" and therefore inherently made of a resilient material.

As for claim 15, the reference recites "tubing used in the instrument are normally constructed of rubber or plastic".

As for claim 18, item 91 shown in figure 3 is a container on plate like item 90. The item 90 may include a plurality of items 91. The items 91 are covered by septum.

As for claims 19 and 20, feed tray 90 is "for transporting one or a plurality of vials of fluid specimens to the injector feed assembly" and is "responsive to automatic control means"

As for claim 26, see discussion above with respect to claims 10, 11, 18.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 4, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Averette (US Patent 4,624,148) in view of Steube et al. (US Patent 6,447,483).

Regarding claims 3, 4, Averette as discussed above does not disclose the inner tube is in the transmission position, wherein the tube assembly can be moved relative to the container so as to cause the end of the inner tube to make contact with the seal and move the inner tube into the piercing position as in claim 3. Averette indeed shows the inner tube is never in contact with the septum wall.

Steube discloses an outer piercing needle 30 with an inner blunt conduit 34 teaching spring bias means 20 which maintains the conduit in a fluid transmission position until the device come in contact with a wall to be penetrated.

Steube further teaches the conduit 34 in the piercing position wherein the conduit returns to the transmission position after the wall is pierced due to the mechanical bias provided by the spring 20 as in claim 4 (see figures 5-7 and column 7 lines 3-24).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a conduit inside a piercing needle biased in a transmission position as this will permit advantageous piercing and repositioning of the conduit for effective fluid communication in one single motion of the device. The action of the device eliminates the need for separate actuation of the conduit to its final position.

As for claim 30, Averette discloses moving the tube assembly but not such that the end of the inner tube contacts the seal and moves into the piercing position. As discussed above with respect to claims 3 and 4, Steube teaches an inner conduit that first contacts the surface to be pierced. Further movement pushes the conduit further inside the piercing needle until it reaches a piercing position as in the instant invention. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the end of the inner tube to contact the seal and move into the piercing position for the same reasons given above.

Claims 8, 22, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Averette (US Patent 4,624,148) in view of Bradley et al. (US Patent 4,577,514).

Regarding claims 8, 22, Averette teaches a source of pressure rather than suction for aspirating the sample.

Bradley discloses a similar tube within a tube sampling device teaching suction source 104 shown in figure 6 for withdrawing a volume of sample (column 5 lines 9-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use suction instead of pressure where a sample may be unacceptably affected by high pressure.

As for claims 23, 24, Averette further recites the "invention relates to improvements in automatic fluid injectors, or automated syringes useful for automatically injecting very small, accurately measured quantities of a fluid into various media, e.g. the inlets of modern analytical instruments such as mass spectrographs or gas chromatographs."

Claims 9, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Averette (US Patent 4,624,148) as modified by Bradley et al. (US Patent 4,577,514) and applied to claim 8 above and further in view of Hrdina (US Patent 3,530,721).

The references as applied above do not teach an injection valve in fluid communication with the inner tube, the injection valve capable of selectively placing the source of suction in fluid communication with the inner tube.

Hrdina teaches slide valve 1 which directs sample drawn through needle 28 by suction pump 17 toward chromatograph column 13.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a slide valve in communication with the suction pump in order to redirect the sample to an analysis device such as a chromatograph column.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Averette (US Patent 4,624,148)

Regarding claim 16, Averette discloses the claimed invention except for the inner tube is made of at least one of the materials chosen from the group of material consisting of nitinol, polymide and Poly Ether Ether Ketone (PEEK).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use one of the materials chosen from the group of material consisting of nitinol, polymide and Poly Ether Ether Ketone (PEEK) for the outer tube, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Averette (US Patent 4,624,148) in view of Glatz et al. (US Patent 5,614,154).

Averette does not teach the inner tube is made of fused silica with a polymide sheath.

Glatz teaches a stabilized fused silica capillary coated with polymide makes a preferred capillary for connecting to PEEK pieces in a chromatographic injection device (column 3 lines 51-57). PEEK pieces are common in chromatographic devices because they are chemically inert, resitant to clogging, have excellent dispersion properties, and mechanically robust.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymide coated or sheathed fused silica capillary as a



Art Unit: 2856

needle as this a preferred material combination for connecting to PEEK pieces preferred for fluid communication in chromatographic devices.

***Allowable Subject Matter***

Claims 5, 6, 28, 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles D. Garber whose telephone number is (571) 272-2194. The examiner can normally be reached on 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

cdg

  
**CHARLES GARBER  
PRIMARY EXAMINER**